JUL 1 7 2000

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ITEM I

510(k) SUMMARY

Safety and Effectiveness

1. Medical Device Establishment:

Syntermed
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Contact person: Kenneth Van Train
Date Summary Prepared: April 18, 2000

2. Medical Device:

Medical Image Merge™ - Software program used for the registration, fusion, and display of medical images.

3. Medical Device Equivalence:

Phoenix Nuclear Medicine Processing Computer, Ref. 510(k) #: K942146.

4. Device Description:

Medical Image Merge (MIM™) is a software program that provides the following functions:

- Image Input/Output – The program can read various file formats including native file formats from multiple medical image manufacturers and DICOM 3.0 standard file formats. An aligned image volume or transformation matrix can be saved using several different file formats.
- Image Volume Display & Manipulation – Multiple windows are used to display the image volume data using various formats. Functions provided to manipulate the displayed images are contrast, image color rendering, image orientation, slice selection, image zoom, display window size, and creation of MIP (Maximum Intensity Projections).
- Image Registration & Alignment – Functions are provided that allow for translation and rotation of one volume set with respect to another in order to produce superimposed data sets. Display functions provided for superimposed data sets are calculation of true color addition of superimposed slices and color table manipulation for optimal display using an eight bit color lookup table, independent color and contrast controls for each of the superimposed image slices, and capability to change the relative percentage contribution of each volume to the final superimposed color image.

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5. Intended Use and Potential Adverse Effect on Health:

This program serves merely as a display and image registration program to aid in the diagnostic interpretation of a patient's study. It was not meant to replace or eliminate other diagnostic tools or medical information at the physician's disposal. The physician should integrate all of the patients' clinical and diagnostic information prior to making his final interpretation. This comprehensive image processing technique (as with all diagnostic imaging) is not perfect, and will be associated with some false positive and false negative results. The expected results and performance of this program in a clinical setting can be found in the data listed in Item H, Testing & Validation. The physician should be aware of the expected performance capabilities when integrating the results into his final interpretation. Therefore, this program has no direct adverse effect on health since the results represent only a part of the information which the physician will utilize for his final interpretation. The final responsibility for interpretation of the study lies with the physician.

6. Marketing History:

There have been several medical device image registration programs marketed in the past which perform similar functions to those performed by the Medical Image Merge™ program. These programs are the Phoenix Nuclear Medicine Processing Computer with Brain Image Registration (K942146), ADAC Laboratories Image Fusion and Review System (K973233), and Marconi's (formerly Picker International) Image Volume Registration program. These programs are all used for the purpose of registration and display of medical images from multi-modalities for the diagnostic interpretation by a physician. MIM™ provides a program which executes in the IDL operating system environment and we believe is substantially equivalent to the Brain Registration program on Siemen's Phoenix Nuclear Medicine Processing Computer, Ref. 510(k) #: K942146. To our knowledge there have been no safety problems with the Brain registration program on the Phoenix Nuclear Medicine Processing Computer which has been in the marketplace for over six years.

7. Conclusions:

The safety of this program has been determined through the various stages of software development which included the initial design, coding, debugging, testing, and validation. The effectiveness of the program has been established in computer simulations studies, in-house semi-quantitative validations which included physician evaluation of registration and fusion effectiveness in 20 patients having SPECT and CT studies. Specific details and results concerning the validation of the Medical Image Merge™ program are listed in Item H, Testing & Validation. We contend that the method employed for the development and the final in-house validation results of this medical display software program, Medical Image Merge™, have proven its safety and effectiveness. In our opinion the Medical Image Merge™ is substantially equivalent to The Brain Fusion program executing on the Siemens Phoenix Nuclear Medicine Processing Computer which has been cleared for marketing. The Medical Image Merge™ program is intended for the same purpose and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2000

Kenneth F. Van Train
President
Official Correspondent
Syntermed
210 Interstate North Parkway, Suite 700
Atlanta, GA 30339

Re: K001276
Medical Image Merge™ (MIM™)
Dated: April 18, 2000
Received: April 21, 2000
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Van Train:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K001276

Device Name: Medical Image Merge

Nuclear Medicine Device

Indication For Use: To detect or image the distribution of radionuclides in the body or organ, using the following techniques(s).

	YES	NO	Energy Range (keV)
A. Planar imaging	___	X	_____
B. Whole body imaging	___	X	_____
C. Tomographic imaging (SPECT) For non Positron emitter	X	___	140 keV
D. Positron imaging by coincidence	X	___	511 keV
E. Positron imaging without coincidence	X	___	511 keV
F. Other indication(s) in the device label, But not included in above list	These Nuclear Images will be merged with images from CT and MRI.		

(Please do not write below this line -- Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001276